1.0 PURPOSE: To lay down procedure for operation and cleaning of Autocoater (Make: Pam Glatt/Glatt).

2.0 SCOPE:

2.1 This procedure is applicable for operation and cleaning of Autocoater (Make: Pam Glatt, Model GCS500 and GCS700, Make: Glatt, Model GCSi 1350).

3.0 RESPONSIBILITY:

3.1 Operator is responsible for the operation and cleaning of Auto coater (Pam Glatt/Glatt) as per the procedure.

3.2 Production Officer/Executive is responsible for operation and monitoring of the procedure.

3.3 Respective department head or designee and Quality assurance personnel is responsible for monitoring, review of the data and take corrective preventive action, if any.

4.0 REFERENCES:

4.1 Operation of PLC for Autocoater (MYCOMP-SOPOSDOPN-0104.)

4.2 Cleaning and Sanitization of Process Room/Other Manufacturing Area (MYCOMP-SOPOSDGEN-0010.)

4.3 Handling of rejects (MYCOMP-SOPOSDGEN-0014)

4.4 Operation and Cleaning of Cleaning In Place System (MYCOMP-SOPOSD OPN-0013)

4.5 Cleaning Validation (MYCOMP-SOP-RQA-GMP-0030)

4.6 Status Labelling (MYCOMP-SOPOSDGEN-0023)

4.7 n process parameters monitoring (MYCOMP-SOP-QA-GMP-0049)

4.8 BPCR writing and review (MYCOMP-SOPOSDGEN-0015)

5.0 DEFENITIONS:

5.1 Nil

6.0 PROCEDURE:

6.1 PRE START UP

6.1.1 If same batch of same product is to be continued: -

6.1.1.1 Check and ensure that machine and room are clean.

6.1.1.2 Check and ensure that the material in the room is of same batch under process.

6.1.1.3 Inform the Quality Assurance Personnel for approval. Do not proceed further until it approved.

6.1.1.4 Remove the cleaning checklist affixed to the equipment and attach to current BPCR after confirming the details.

6.1.1.5 Update the label, 'Equipment/Room Status' (MYCOMP-SOP-SD-GEN-0023 Attachment 7.1), to the equipment with necessary details and sign in Status Production.

6.1.2 If next batch of same product is to be continued: -

6.1.2.1 Check and ensure that machine and room are clean and previous batch documents are removed.

6.1.2.2 Inform the Quality Assurance Personnel for approval. Do not proceed further until it approved.

6.1.2.3 Remove the cleaning checklist and attach to current Batch Production and Control Record after confirming the details.

6.1.2.4 Update the label, 'Equipment/Room Status' (MYCOMP-SOP-SD-GEN-0023 Attachment 7.1), to the equipment with necessary details and sign in Status Production.

6.1.3 If new product is to be taken on the Machine: -

6.1.3.1 Check and ensure that machine and room are clean and previous product documents are removed.

6.1.3.2 Inform the Quality Assurance Personnel for approval. Do not proceed further until it approved.

6.1.3.3 Remove the cleaning checklist affixed to the equipment and attach to current Batch Production and Control Record after confirming the details.

6.1.3.4 Update the label, 'Equipment/Room Status' (MYCOMP-SOP-SD-GEN-0023 Attachment 7.1), to the equipment with necessary details and sign in Status Production.

6.2 **START UP**

6.2.1 Check the environmental condition i.e. temperature, relative humidity and differential pressure, proceed further if these conditions are within limit as specified in the Batch Production and Control Record.

6.2.2 In case of non-compliance do not proceed further, till it is rectified.

6.2.3 Check the Preventive Maintenance status of machine for its due date.

6.2.4 Check the material to be processed, for Identification, Product name, Batch Number and quantity from the status label and material issue slip.

6.2.5 Bring the coating material near Autocoater for processing.

6.2.6 Do not touch any moving part of machine during operation.

6.2.7 Weigh the quantity of the purified water and/or solvent used for the coating solution preparation using weighing balance in the coating area.

6.2.8 Prepare coating solution as per Batch Production and Control Record using mechanical stirrer or prepare in coating solution tank connected with pneumatic stirrer and compressed air.

6.2.9 Load the tablet into the coating pan.

6.2.10 Transfer the coating solution tank on the weighing balance connected to the coating machine.

6.2.11 Connect the silicon tubing through the peristaltic pump and connect one end of the tube to the spray gun inlet pipe and other end to coating solution storage tank.

6.3 **OPERATING PROCEDURE**

6.3.1 **<u>Operating procedure of Autocoater (PAM GLATT): -</u>**

6.3.1.1 Release the emergency switch, switch on the touch screen panel and enter username and password

6.3.1.2 Ensure that the compressed air pressure is NLT 4.0 Kg/cm^2.

6.3.1.3 Follow the procedure for “Operation of PLC for Autocoater” (MYCOMP-SOPOSDOPN-0104).

6.3.1.4 Set and select the product recipe.

6.3.1.5 **Spray Rate Setting:**

6.3.1.5.1 Take out the spray gun arm assembly.

6.3.1.5.2 Connect one end of the Controlled Air quick release coupling and Atomization Air quick release coupling to the machine and the other end to the spray gun bar.

6.3.1.5.3 Use a big size polybag and attached to the spray gun arm assembly to collect the spray solution from all the guns collectively.

6.3.1.5.4 Select “Auto mode”.

6.3.1.5.5 On “Parameter” screen feed the atomization air pressure to zero and desired peristaltic pump RPM.

6.3.1.5.6 Start the spray test and collect the coating solution in the polybag. Continue the spray test until all the solution flow from each gun is uniform. Stop the spray test, remove the polybag and discard.

6.3.1.5.7 Use tared sample polybags for weighing the coating solution for verification of the spray rate. Hold the sample polybag at each spray gun.

6.3.1.5.8 Start Spray test, the solution shall start flowing through each spray gun without atomization. Collect the coating solution in each tared polybag for one-minute. Weigh individual spray solutions from each gun. Stop the spray test, calculate and record the average spray rate in “Coating Monitoring Record of Tablets” attached in BPCR.

6.3.1.5.9 Increase or decrease the peristaltic pumps RPM to increase or decrease the spray rate.

6.3.1.5.10 If required perform the spray rate again for uniform spray rate.

6.3.1.5.11 Discard the polybags and solution.

6.3.1.6 **Spray Pattern Setting:**

6.3.1.6.1 Verify the spray pattern by setting atomization pressure as per the Batch Production and Control Record. Set the gun-to-gun distance for effective spray pattern. Set the optimum spray pattern by rotating the Atomization Air Fan setting knob “Clockwise or Anticlockwise” or set pattern air on

IPC as applicable. Hold the stainless-steel tray in front of the guns, keeping the distance between tray and gun similar to the distance between gun and bed. Start “Spray Test” and verify the spray pattern on the SS tray. The spray pattern shall be uniform and shall not overlap with other guns spray pattern.

6.3.1.6.2 If required perform the spray pattern again for optimum spray pattern.

6.3.1.6.3 Stop the “Spray Test”.

6.3.1.6.4 Record the spray pattern verification whether it is OK or NOT OK in Coating Monitoring Record of Tablets (MYCOMP-SOP-QA-GMP-0049 Attachment 7.12).”

6.3.1.6.5 Remove the quick air release connectors of controlled air and atomization air.

6.3.1.7 Take in the gun arm assembly, fix the quick air release connectors of controlled air and atomization air.

6.3.1.8 Before start the coating machine, set the DP pan -50 to 0, Air flow in between 2000 to 3500 CFM and spray pump rpm as per required spray rate or as per mentioned in respective BPCR.

6.3.1.9 Press Start option to start the coating process.

6.3.1.10 Press the “Status option” to view the online status of Scrubber Pump/Spray Pump, Exhaust Blower, Inlet Blower, Heater, Pan, and Atomizing Air.

6.3.1.11 Refer the “Parameter” screen to monitor and record the operation parameters at the intervals mentioned in the BPCR.

6.3.1.12 Following procedure shall be followed for coating machine stoppage during operation:

6.3.1.12.1 Stop the spray by stopping peristaltic pump.

6.3.1.12.2 Stop the machine by pressing stop key and take out the spray gun arm assembly.

6.3.1.12.3 Keep the coating pan in inching mode.

6.3.1.12.4 This procedure shall be followed during each breaks and interruptions. The details of interruptions shall be recorded in BPCR.

6.3.1.12.5 To restart the coating process, set the inlet temperature and Pan RPM to previous set value or as required as per Batch Production and Control Record. Press the auto start button. Once the exhaust temperature is achieved, spraying will start automatically at set spray rate.

6.3.1.13 Always collect sample through sampling port by sampling spatula.

6.3.1.14 Stop the spray when percentage weight gain is achieved as per Batch Production Control Record. Set the spraying cycle value to the current value. Post jog cycle will start automatically and dry the coated tablets for the specified time and parameters as per the Batch Production Control Record and then cool the tablets as specified in the Batch Production Control Record. Check the percentage weight gain and record the same in Batch Production Control Record.

6.3.1.15 Check the Physical parameter of coated tablets as per description of Batch Production and Control Record.

6.3.1.16 Disconnect the quick release couplings of atomization air and controlled air.

6.3.1.17 Take out the spray arm assembly.

6.3.1.18 To unload the tablet, connect the discharge chute assembly, press Discharge Option on IPC and unload the tablets in the duly labeled (Status label manufacturing-coated, MYCOMP-SOPOSDGEN-0023 Attachment 7.19 or MYCOMP-SOPOSD GEN-0023 Attachment 7.20) double poly bag lined container or as specified in the BPCR or if required unload the tablets manually with the help of SS bowl. Write the weighing details of HDP containers in the Batch Production and Control Record.

6.3.1.19 Write the production details in the Batch Production and Control Record and equipment log book.

6.3.1.20 Delete the loaded parameters from the batch screen. New parameters shall be loaded for products in campaign.

6.3.2 **Operating procedure of Autocoater (GLATT): -**

6.3.2.1 Release the emergency Switch, switch on the touch screen panel and enter username and password.

6.3.2.2 Ensure that the compressed air pressure is NLT 4.0 Kg/cm².

6.3.2.3 Follow the procedure for “Operation of PLC for Autocoater” (MYCOMP-SOPOSDOPN-0104).

6.3.2.4 Wait for the system to boot and the startup screen shall appear, which contains Edit Recipe & Batch Mode.

6.3.2.5 Select the login icon, a login screen appears. Fill the suitable details and log in.

6.3.2.6 **Preparation of New Recipe:**

6.3.2.6.1 Press the “EDIT RECIPE’ icon screen.

6.3.2.6.2 Then press the “COATING” icon.

6.3.2.6.3 Select the operation type from the list like Charging, Conditioning Coater, Film Coating, conditioning, Discharge Front and Stop Coater.

6.3.2.6.4 Edit the Operation name as per as per Batch Production and Control Record (BPCR) like Charging, Pre-warming, Coating, Drying and Cooling, Discharge and Stop Coater.

6.3.2.6.5 Press  icon and enter product name to save the recipe with product name.

6.3.2.6.6 Press the  icon.

6.3.2.6.7 Press the “AUTHORIZE” icon for authorizing the recipe.

6.3.2.6.8 Select the Product, press the  icon and authorize the product for production. After authorization of product press the  icon to go the previous screen.

6.3.2.6.9 Press the Batch (F2) icon.

6.3.2.6.10 Select the "I want to produce" popup icon and press the 

icon to select the recipe, select the recipe and then press the 

icon.

6.3.2.6.11 Enter the Batch number & lot no. as per BPCR and press the 

icon.

6.3.2.6.12 Enter the Product name, solution quantity and lot size as per BPCR and press the 

con.

6.3.2.6.13 If everything is ok select the 

icon to save the recipe.

6.3.2.6.14 Press the  icon to edit the process parameters as per BPCR in the selected operation phase if required. Press exit icon after setting the data in every process operation to go to the next process operation.

- For Charging
- For Pre-Warming
- For Spraying
- For Drying
- For Cooling
- For Discharging
- For Stop Coater

6.3.2.7 **Spray Rate Setting:**

6.3.2.7.1 Take out the spray gun arm assembly.

6.3.2.7.2 Press the Function icon (F8) and select the Spray test film / spray test.

6.3.2.7.3 Set the atomization air pressure to zero and enter the desired peristaltic / spray pump RPM (if applicable).

6.3.2.7.4 Use a big size polybag and attached to the spray gun arm assembly to collect the spray solution from all the guns collectively.

6.3.2.7.5 Press On the “Spray Unit Filling Film”/ “Spray unit filling” icon to start the peristaltic pump and.

6.3.2.7.6 Collect the coating solution in the polybag. Continue the “Spray Unit Filling Film” until the solution flow from each gun is uniform. “Off” the “Spray Unit Filling Film”/ “Spray unit filling”, remove the polybag and discard the polybag with coating solution.

6.3.2.7.7 Use tared sample polybags for weighing the coating solution for verification of the spray rate. Hold the sample polybag at each spray gun.

6.3.2.7.8 On the “Spray Unit Filling Film”/ “Spray unit filling”.

6.3.2.7.9 The solution shall start flowing through the spray gun, without atomization. Collect the coating solution in each tare polybag for one-minute, Weigh individual spray solutions from each gun. Calculate and record the average spray rate in “Coating Monitoring record of Tablets” attached in BPCR.

6.3.2.7.10 “Off” the “Spray Unit Filling Film”/ “Spray unit filling”.

6.3.2.7.11 Increase or decrease the spray pumps RPM to increase or decrease the spray rate.

6.3.2.7.12 If required perform the spray rate again for uniform spray rate

6.3.2.7.13 Discard the polybags and spray solution.

6.3.2.8 **Spray Pattern Setting:**

6.3.2.8.1 Select Yes “Enable spray test”, press “on” the “Spray test film” option and start the “Spray Test Film” and verify the spray pattern on the Stainless-Steel tray. The spray pattern shall be uniform and shall not overlap with other guns spray pattern.

6.3.2.8.2 Verify the spray pattern by setting atomization pressure as per the Batch Production and Control Record. Set the gun-to-gun distance for effective spray pattern. Set the optimum spray pattern by rotating the atomization Air Fan setting Knob

"Clockwise or Anticlockwise". Hold the SS tray in front of the gun, keeping the distance between tray and gun similar to the distance between gun and bed.

6.3.2.8.3 If required perform the spray pattern again for optimum spray pattern.

6.3.2.8.4 Press "Off" the "Spray Test Film" option and select the "No" Enable spray test".

6.3.2.8.5 Record the spray pattern verification whether it is OK or NOT OK in "Coating Monitoring Record of Tablets" (MYCOMP-SOP-QA-GMP-0049 Attachment 7.12)

6.3.2.9 The Auto mode or Manual mode shall be changed by pressing the Manual/Auto icon.

6.3.2.10 Take in the spray gun arm assembly.

6.3.2.11 Refer the Parameter Screen to monitor and record the operation parameters at the intervals mentioned in the Batch Production and Control Record.

6.3.2.12 Press  icon to start the coating operation as per set parameters.

6.3.2.13 Press the  icon to hold the coating operation.

6.3.2.14 Press the  icon to stop the coating operation.

6.3.2.15 Press the  icon to jump the next operation level. A pop up screen shall appear for confirming the jump to the next operation level.

6.3.2.16 Press the  icon to jump the previous operation level. A pop up screen shall appear for confirming the jump to the next operation level.

6.3.2.17 Go to Batch screen and press  icon to start the operation in Auto or Manual Mode.

6.3.2.18 Pre-warm the tablets in intermittent mode as per the instructions of the BPCR. Record the details of pre-warming.

6.3.2.19 After prewarming start the Spraying.

6.3.2.20 Check the physical appearance intermittently for proper coating and quality of tablet.

6.3.2.21 Always collect the sample through sampling port by spatula.

6.3.2.22 Check the coating parameters such as inlet temperature, exhaust temperature, pan RPM, peristaltic pump RPM and atomization air pressure, DP pan, spray rate as per the frequency mentioned in “In process parameter monitoring” (MYCOMP-SOP-QA-GMP-0049) and record the same.

6.3.2.23 Following procedure shall be followed for coating machine stoppage during operation:

6.3.2.23.1 This procedure shall be followed during each breaks and interruptions. The details of interruptions shall be recorded in BPCR.

6.3.2.23.2 Stop the spray by stopping peristaltic pump.

6.3.2.23.3 Stop the machine by pressing stop key and take out the spray gun arm assembly.

6.3.2.23.4 Keep the coating pan in inching mode.

6.3.2.23.5 To restart the coating process, set the inlet temperature and Pan RPM to previous set value or as required as per BPCR. Press the auto start button. Once the exhaust temperature is achieved, spraying will start automatically at set spray rate.

6.3.2.24 Check differential pressure of pan at the start and until the completion of coating operation.

6.3.2.25 Continue the coating operation until the desired weight build up achieved as specified in BPCR.

6.3.2.26 Stop the spray by pressing  icon once the desired weight builds up is achieved as per Batch Production Control Record.

6.3.2.27 Reduce the Pan rpm, go to the next operation by pressing the  icon and dry the coated tablets for the specified time & parameters as per the Batch Production Control Record.

6.3.2.28 Close inlet blower and allow tablet to cool.